IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

ALISSA DREGER,

Plaintiff,

v.

Case No. 2:20-cv-3814
Judge Michael H. Watson
Magistrate Judge Elizabeth P. Deavers

KLS MARTIN, LP,

Defendant.

OPINION AND ORDER

This matter is before the Court to consider the Motion for a Protective Order filed by Defendant KLS Martin, L.P., (ECF No. 58), and the corresponding Motion to Compel filed by Plaintiff Alissa Dreger, (ECF No. 65). Plaintiff also has filed a motion for leave to amend her motion to compel, citing a need to correct clerical errors. (ECF No. 71.) This latter motion (ECF No.71) is unopposed and, therefore, is **GRANTED**. Accordingly, for purposes of this Opinion and Order, the Court will consider ECF No. 65 as amended by ECF No. 71-1. Thus, the competing discovery motions have been fully briefed**.** (*See also* ECF Nos. 70, 72.) For the following reasons, the motions are **GRANTED, in part, and DENIED, in part**. Because the Court is able to resolve these matters on the basis of the parties' briefing, Defendant's request for oral argument is **DENIED.**

I.

Federal Rule of Civil Procedure 37 permits a party to file a motion for an order compelling discovery if another party fails to respond to discovery requests, provided that the motion to compel includes a certification that the movant has, in good faith, conferred or

attempted to confer with the party failing to respond to the requests. Fed. R. Civ. P. 37(a)(1). Here, the Court is satisfied that this prerequisite has been satisfied.

Determining the scope of discovery is within the Court's discretion. *Bush v. Dictaphone Corp.*, 161 F.3d 363, 367 (6th Cir. 1998). Unless the court orders otherwise, the scope of discovery is that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). The Court can, and indeed must, limit the frequency or extent of discovery "if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1)." *Planned Parenthood Sw. Ohio Region v. Hodges*, No. 1:15-CV-00568, 2019 WL 13044827, at *2 (S.D. Ohio Mar. 31, 2019) (citing Fed. R. Civ. P. 26(b)(2)(C)). The Court also has discretion to limit the scope of discovery by issuing protective orders, for good cause shown, forbidding the requested discovery "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Fed. R. Civ. P. 26(c).

The Federal Rules of Civil Procedure grant parties the right to "obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1); *see also Siriano v. Goodman Mfg. Co., L.P.*, No. 2:14-CV-1131, 2015 WL 8259548, at *5 (S.D. Ohio Dec. 9, 2015). "*Relevance* is construed very broadly for discovery purposes." *Doe v. Ohio State Univ.*, No. 2:16-CV-171, 2018 WL 1373868, at *2 (S.D. Ohio Mar. 19, 2018) (emphasis in original) (citation omitted). Despite being construed broadly, the concept of relevance is not unlimited. *Averett v. Honda of Am. Mfg., Inc.*, No. 2:07-cv-1167, 2009 WL

799638, at *2 (S.D. Ohio March 24, 2009). Indeed, "[t]o satisfy the discoverability standard, the information sought must have more than minimal relevance to the claims or defenses." *Doe*, 2018 WL 1373868 at *2 (citations omitted). Furthermore, when information is "negligibly relevant [or] minimally important in resolving the issues" this will not satisfy the standard. *Id.* (citation omitted).

"[T]he Federal Rules of Civil Procedure instruct district courts to limit discovery where its 'burden or expense. . . outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.'" *Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 305 (6th Cir. 2007) (quoting former Fed. R. Civ. P. 26(b)(2)(C)(iii)). This Court has previously held that "[t]hese factors are retained in revised Fed. R. Civ. P. 26(b)(1), reflecting 'their original place in defining the scope of discovery' " because " 'restoring proportionality' is the touchstone of revised Rule 26(b)(1)'s scope of discovery provisions." *Siriano*, 2015 WL 8259548, at *5 (citing Fed. R. Civ. P. 26(b)(1)). In analyzing the extent of the burden on the producing party, the Court of Appeals for the Sixth Circuit "has held that limiting the scope of discovery is appropriate when compliance 'would prove *unduly* burdensome,' not merely expensive or time-consuming." *Id.* (citing *Surles*, 575 F.3d at 305) (emphasis in original).

II.

This products liability action, filed on July 29, 2020, asserts claims for, *inter alia*, manufacturing defect, design defect, failure to warn, and failure to conform to representation. (Complaint, ECF No. 1.) These claims arise from two surgical procedures in which a rib plate and associated screws sold by Defendant were implanted into and explanted from Plaintiff.

Despite Defendant's characterization of this case as a "straightforward" and "simple" products liability action, this is not the first combative discovery dispute the parties have called upon the Court to resolve.

The current dispute centers largely on discovery related to other similar incidents. In the context of this dispute, Defendant accuses Plaintiff of blowing the scope of discovery out of proportion while Plaintiff counters that Defendant is withholding information considered fundamental in products liability cases. The particular documents at issue here include Medical Device Reports ("MDRs") and documents other than MDRs, including complaint files, product complaints, and documentation of CAPA-related activities as reflected in Requests for Productions Nos. 1, 2 and 3 in Plaintiff's Second Set of Requests for Production and Interrogatory No. 1 in Plaintiff's Second Set of Interrogatories. These requests appear to be addressed to documents and information relating specifically to the "Rib Plate" (Model Number 24-015-22-71), *i.e.,* the same model number implanted into and explanted from Plaintiff's body, and more broadly to what Plaintiff has deemed the "KLS Martin Thoracic Plating System," *i.e.*, similar thoracic plates ("Other Plate Models"). (For purposes of the current dispute, Plaintiff confirms that she seeks documents or information relating only to other *plates* and not any associated "rib screws" or instruments. S*ee* ECF No. 65 at 5 n. 4.) Also at issue are Defendant's obligation to produce a privilege log and to produce certain documents belonging to KLM.

Defendant's view, simply stated, is that Plaintiff is entitled only to a copy of MDRs relating to the "Subject Rib Plate" (the specific device implanted into and later explanted from Plaintiff's body), a properly redacted copy of which it already has provided to Plaintiff. (ECF No. 58 at 6 n. 4.) Consistent with its view that Plaintiff is not entitled to any information related

to similar incidents, Defendant has objected to the discovery requests on numerous grounds. In large part, Defendant asserts that certain statutes and regulations governing the adverse event reporting program administered by the United States Food and Drug Administration ("FDA") control here and prohibit the requested discovery. Beyond this, Defendant argues that the requests incorporate overly broad definitions; cover a seventeen-year time period; are not limited to documents in its possession; seek privileged information or information subject to work product protection; seek irrelevant documents; are not proportional to the needs of the case; and generally are overbroad and unduly burdensome. Defendant seeks a protective order addressed not only to these specific requests but also to "any substantially similar discovery requests" Plaintiff may issue in the future.

Defendant, however, explains that the FDA maintains a free Manufacturer & User Facility Device Experience ("MAUDE") Database that provides publicly-available and appropriately disclosable versions of MDRs it has received and suggests that Plaintiff's referral to this Database is a reasonable resolution here. (ECF No. 58 at 13.) Thus, in sum, Defendant objects to any discovery directed to both the "Rib Plate" (Model Number 24-015-22-71), *i.e.,* the same model implanted into and explanted from Plaintiff's body, and to what Plaintiff has described as "similar thoracic plates that comprise the KLS Martin Thoracic Plating System" ("Other Plate Models").[1] Defendant also has declined to provide a privilege log, arguing that one is not required because any withheld documents are not "otherwise discoverable" as contemplated by Fed.R.Civ.P. 26(b)(5). Finally, Defendant contends that it has no obligation or

[1] Plaintiff confirms that, with respect to this "System," she is not seeking documents for "rib screws" or instruments, only plates. (ECF No. 65 at 5.)

ability to produce documents belonging to KLM because it does not possess or control such documents.

For her part, Plaintiff argues that she is entitled to discover evidence of similar incidents, including MDRs and other documents, because such evidence is relevant to causation, Defendant's knowledge of any alleged defect and potential harm, and Defendant's failure to warn. With respect to the MDRs, Plaintiff confirms that she already has accessed the MAUDE Database and obtained any publicly-available MDRs. (ECF No. 65 at 12.). Thus, she is seeking only MDRs that are not available in that Database. (*Id.*) Further, she confirms that she has agreed to redactions as appropriate to protect the identities of the patients, reporters, etc. associated with other incidents. (ECF No. 65 at 5.) As for discovery related to Other Plate Models more specifically, Plaintiff argues that the information she seeks is relevant because these "other models are made of the same material, are used for the same purpose, function in the same manner, and feature the same design (particularly those that are rib plates)." (ECF No. 65 at 14.) Plaintiff also contends that Defendant and KLM are under common ownership and because Defendant is KLM's agent for purposes of medical device reporting in the United States, Defendant must be considered to have control over documents in KLM's possession. Additionally, Plaintiff asserts that Defendant cannot claim privilege and then fail to provide a privilege log to enable Plaintiff 's evaluation of those privilege claims. Finally, Plaintiff argues that Defendant is required to maintain a CAPA system – designed to provide notice of dangers – and that Defendant must disclose documents relating to this system. (ECF No. 65 at 6.) Based on all of the above, Plaintiff has for an award of sanctions against Defendant under Fed.R.Civ.P. 37.

III.

Plaintiff's Complaint alleges, in part, that the KLS rib plate was defective and that Defendant had actual prior knowledge of a risk its rib plates would break during the chest expansion and contraction of ordinary breathing and failed to provide a warning, all in violation of Ohio Revised Code §§ 2307.74 – 2307.77. Accordingly, the starting point for the Court's analysis is whether any of the requested discovery at issue addressed to similar incidents is relevant to any of these claims or whether, consistent with Defendant's view, relevant information is limited to only that relating to the Subject Rib Plate.

A. Relevance

This Court and other courts considering the relevancy of inquiries similar to those made by Plaintiff here have concluded that generally, "discovery relating to 'similar, if not identical [product] models'" is permissible." *Kroft v. Broan-Nutone, LLC*, No. 2:11-CV-388, 2012 WL 13026969, at *2 (S.D. Ohio Apr. 5, 2012) (citing *Tolstih v. L.G. Electronics*, No. 2:07-CV-582, 2009 WL 439564, at *5 (S.D. Ohio Feb. 20, 2009) (quoting *Holfer v. Mack Trucks, Inc.*, 981 F.2d 377, 380–81 (8th Cir. 1992)); *see also Reising v. Toro Co.,* No. 1:17-CV-00431, 2018 WL 5489568, at *4 (S.D. Ohio Oct. 29, 2018); *Hennigan v. G.E. Co.*, No. 09-11912, 2010 WL 4189033, at *5 (E.D. Mich. Aug. 3, 2010)). Of course, "[p]rior accidents or incidents must be 'substantially similar' to the one at issue before they will be admitted into evidence." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.,* 505 F. Supp. 3d 770, 781–82 (S.D. Ohio 2020) (Sargus, J.) (quoting *Rye v. Black & Decker Mfg. Co.*, 889 F.2d 100, 102 (6th Cir. 1989)). "Typically, this requires 'that the accidents must have occurred under similar circumstances or share the same cause.'" *Id.* Indeed, "[p]ermitting discovery of models that are not substantially similar is truly the equivalent of comparing apples and oranges where there are differences between the other models and the model at issue." *Reising, supra*, at *4

(quoting *Tolstih*, *supra*, at *5 (citation and internal quotation omitted)). "Evidence of prior incidents may demonstrate that a defendant was on notice or had knowledge of the risks giving rise to the incident." *Davol,* 505 F. Supp. 3d at 781-782 (citing *Koloda v. Gen. Motors Parts Div., Gen. Motors Corp.*, 716 F.2d 373, 375–76 (6th Cir. 1983)). Neither "great specificity nor perfectly identical circumstances, are required to show substantial similarity. *Id.* at 782.

Accordingly, putting issues of FDA statutes and regulations and the breadth or undue burden of Plaintiff's requests as framed aside for the moment, discovery relating to the "Rib Plate" (Model Number 24-015-22-71) is relevant.[2] Stated another way, "'[i]t would be difficult, if not impossible, for a plaintiff to make a showing that other incidents are substantially similar, if they are precluded from discovery of that information in the first place.'" *Kroft*, 2012 WL 13026969 at *4 (quoting *Hennigan*, 2010 WL 4189033 at *5). Thus, the motion for a protective order is **DENIED** to the extent that it relies on a relevance challenge to prohibit any discovery relating to the Rib Plate. Instead, the parameters of the permissible discovery will be addressed more specifically below.

With respect to other models, Plaintiff acknowledges that the discoverability of information relating to different models turns on whether those models "'share with the accident-causing model those characteristics pertinent to the legal issues raised in the litigation.'" *Tolstih*, 2009 WL 439564 at *5 (quoting *Fine v. Facet Aerospace Products Co.*, 133 F.R.D. 439, 441 (S.D.N.Y. 1990)).[3] In determining whether discovery of a different model is permissible under

[2] Presumably, although the parties' briefing does not make this clear, this Model Number can be further described as a "20 hole, 1.5 mm thick X-shape rib fixation plate." (Quigley Affidavit, ECF No. 70-1 at ¶ 18).

[3] The Court noted in *Davol* that, when introduced to demonstrate notice or knowledge, a lesser degree of similarity may be required if the incident would have alerted the defendant. 505 F. Supp. 3d at 781–82. As set forth above, Plaintiff argues in terms of substantial similarity and makes no claim-dependent distinction.

Rule 26, courts should undertake a "fact specific inquiry . . . to determine the extent of the similarities or dissimilarities between models." *Reising,* 2018 WL 5489568, at *4. Further, it is Plaintiff's burden to identify these "pertinent characteristics." *See*, *e.g.*, *Menendez v. Wal-Mart Sores East L.P.*, No. 1:10-CV-00053, 2010 WL 3088440, at *2 (N.D. Ind. Aug. 4, 2010) (declining to compel discovery on additional models unless the plaintiffs "produce[d] an expert opinion identifying certain 'pertinent characteristics' that would be relevant in determining 'substantially similar' [models]"); *Tolstih*, 2009 WL 439564 at *7 (implicitly acknowledging that the plaintiff has the burden to "demonstrate that [the] different models were substantially similar and therefore relevant"); *Lohr v. Stanley-Bostich, Inc.*, 135 F.R.D. 162, 164 (W.D. Mich. 1991) (plaintiff, through his expert, identified the product features that caused or contributed to his injury, prompting the court to permit discovery into other products containing the identified features).

Consistent with the above authority, Plaintiff relies on the Declaration of Dr. David Paulus, its retained expert. (ECF No. 65-1.) According to Dr. Paulus, he has been retained in the past to review two other plates from the KLS Martin Thoracic Plating System line. Of those two plates, one was a sternum locking plate and the other was a similar rib plate. (*Id*. at ⁋ 7.) In his professional opinion, these devices share the following common features: they are fashioned from commercially pure titanium; the different rib plate models share a design commonality featuring a series of connected and alternating counter-sunk bone screw holes, while the sternum plate similarly features counter-sunk holes which are in one line instead of alternating; these thoracic plating systems likely share a common manufacturing process; these thoracic plating systems are all attached directly to broken bones by means of bone screws; and the rib plates are intended to hold the broken bone ends together until healing occurs. (*Id*. at ⁋ 8.) In his

professional opinion, the three thoracic plating systems he has studied more likely than not failed in the same manner when affected by the movement of the chest during respiration and this design defect, for the same reasons, more likely than not affects other models in the KLS family of thoracic plating systems. (*Id*. at ¶¶ 9, 10.)

For its part, Defendant impugns the validity of Dr. Paulus's Declaration, noting his lack of detail and its speculative assertions, and submits the Affidavit of Carson Quigley, a Biomedical Engineer and its Product Manager for sternal and rib products, including rigid fixation plating products comprised of plates and screws for application to the bones in the human sternal thoracic cavity. (ECF No. 70-1 at ¶ 2.) In short, Ms. Quigley explains in detail that "the three KLS plates Dr. Paulus has reviewed are of different types and thicknesses, were designed for different purposes, were manufactured using different methods, and were applied to three completely different parts of the bodies of three different patients who had three different surgical procedures to address three different medical issues." (*Id*. at ¶ 21.)

The matter of discovery into incidents involving other product models does not warrant significant discussion. On the current record, Plaintiff has failed to demonstrate that the Other Plate Models possess characteristics pertinent to the legal issues raised in this litigation. As Defendant points out, Dr Paulus's Declaration is comprised of speculation and a very limited review of Defendant's products. These shortcomings are particularly stark when contrasted with the detailed explanations of certain other products set forth in Ms. Quigley's Affidavit. Accordingly, the motion for a protective order is **GRANTED** as to Request for Production No. 2 on grounds of relevance and Plaintiff's motion to compel in this regard is **DENIED.**

B. MDRs

As noted, Plaintiff confirms in her briefing that with respect to MDRs, she seeks only those that are not available in the MAUDE Database. (ECF No. 65 at 12.) In response to this

confirmed limitation, Defendant represents that it has no such MDRs. (ECF No. 70 at 10-11.) Ordinarily, the representation of a party's attorney that no documents exist is sufficient to defeat a motion to compel absent credible evidence that the representation is inaccurate. *Brown v. Tellermate Holdings Ltd.*, No. 2:11-CV-1122, 2013 WL 1363738, at *6 (S.D. Ohio Apr. 3, 2013). Consequently, if Plaintiff "'do[es] not provide any evidence demonstrating that responsive documents do, in fact, exist and are being unlawfully withheld, [her] motion to compel must fail.'" *Id.* (quoting *Alexander v. F.B.I.,* 194 F.R.D. 299, 301 (D.D.C. 2000). Here, she has not done so. Of course, trial counsel have an affirmative obligation to insure that what their clients tell them is accurate. The Court presumes that they have discharged their duties in this case. *Id.* (citing *Bratka v. Anheuser–Busch Co., Inc.,* 164 F.R.D. 448 (S.D. Ohio 1995)). Accordingly, Defendant's motion for a protective order is **GRANTED** as to any MDRs not available in the MAUDE Database and Plaintiff's motion to compel is **DENIED**.

C. CAPA System

Plaintiff contends that Defendant is required to maintain a "CAPA System" in accordance with 21 C.F.R. § 820.100. According to Plaintiff, the notice of dangers, or lack thereof, these CAPA policies and procedures provide is relevant to her claims here. Defendant explains, however, that it is not required to maintain such a system and that the current dispute over CAPA-related activities results from Plaintiff's misunderstanding of the applicable FDA regulations. The Court agrees.

As the Court understands it, Plaintiff believes that, because Defendant is a manufacturer for purposes of 21 C.F.R. § 803, it also is a manufacturer for purposes of 21 C.F.R. § 820.3. This belief, however, is misplaced because the two sets of regulations have distinct definitions of "manufacturer." For example, 21 C.F.R. § 803 addresses Medical Device Reports. Defendant

explains that, for purposes of medical device reporting, it falls within the definition of manufacturer because it is the initial distributor of a foreign entity. *See* 21 C.F.R. § 803.3(l)(4). (ECF No. 70 at 22-23.) The regulations set forth in 21 C.F.R. § 820, however, relate to Quality System Regulation. For purposes of those regulations, "manufacturer" is defined as follows:

> (o) Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

21 C.F.R. § 820.3. Subpart J contains the regulations applicable to "Corrective and Preventative Action." 21 C.F.R. § 820.100. Defendant explains that, for purposes of 21 C.F.R. § 820, it is a repackager/relabeler and, as such, it maintains a QMS system designed to address packaging and labeling issues. Defendant further asserts that its QMS system would only generate a CAPA document if a repackaging/relabeling issue arose but it never has with respect to rib fixation products. As a result, it has no documents responsive to Plaintiff's CAPA-related request. (ECF No. 70 at 25.) Defendant's explanation appears consistent with the scope of the relevant regulations. *See* 21 C.F.R. § 820.1. ("This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.") Plaintiff sets forth no meaningful authority to the contrary, instead relying on her own interpretations of the various regulations. Accordingly, the motion for a protective order is **GRANTED** and the motion to compel is **DENIED** as to any documents "evidencing its CAPA System."

D. Complaint files, product complaints and remaining issues

The current discovery dispute has evolved as reflected in the parties' briefing and, in light of the conclusions reached above, such that the crux of the debate is the discoverability of complaint files and product complaints relating to the "Rib Plate" (Model Number 24-015-22-71) ("20 hole, 1.5 mm thick X-shape rib fixation plate"). The resolution of this issue also will impact any obligation Defendant may have to produce a privilege log or to obtain documents from KLM. The Court will address each of these issues, as necessary, in turn.

Turning first to the matter of the discoverability of Defendant's complaint files and product complaints, Defendant explains that these items are protected from discovery under applicable statutes and regulations governing FDA reporting, specifically 21 U.S.C. § 360i(b)(3) and 21 C.F.R. 20.63(a) and (f). The statutory provision, 21 U.S.C. § 360i(b)(3), pertains to "User Reports" and provides, as relevant, that:

> **(3)** No report made under paragraph (1) by--
>
> **(A)** a device user facility,
> **(B)** an individual who is employed by or otherwise formally affiliated with such a facility, or
> **(C)** a physician who is not required to make such a report,
>
> shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

21 U.S.C. § 360i(b)(3). The relevant regulations set forth in 20 C.F.R. § 20.63 provide as follows:

> (a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.
> …
>
> (f) The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic,

> or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

21 C.F.R. § 20.63.

As previously discussed, Defendant is a "manufacturer" for purposes of medical device reporting. (ECF No. ECF No. 70 at 22 "… just because KLS qualifies as a 'manufacturer' for the limited purpose of medical device reporting…."). Consistent with the express applicability of § 360i(b)(3) to "User Reports," courts have recognized that manufacturer reports are not addressed by § 360i(b). *In re Davol,* 505 F. Supp. 3d at 780. Instead, manufacturer reports are addressed by § 360i(a). *Id*. Accordingly, courts have held that § 360i(b)(3) does not apply to manufacturer reports. *Id.* ("Though no binding precedent is on point, the vast majority of courts to consider this question or similar ones have reached the same interpretation of § 360i(b)(3).") (citing *Coolidge v. United States*, No. 10-CV-363S, 2018 WL 5919088, at *2 (W.D.N.Y. Nov. 13, 2018) (citing cases); *Kubicki ex rel. Kubicki v. Medtronic*, 307 F.R.D. 291, 298 (D.D.C. 2014) (considering discoverability rather than admissibility); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, Nos. 2:12-MD-02327, 2:12-cv-4301, 2014 WL 505234, at *5 (W. Va. Feb. 5, 2014) (citing *Chism v. Ethicon Endo-Surgery, Inc.*, No. 4:08CV00341-WRW, 2009 WL 3066679, at *1 (E.D. Ark. Sept. 23, 2009)). Defendant attempts to claim the protection of 21 U.S.C. § 360i(b)(3) by explaining that the complaints it receives only come "from protected

mandatory device user facilities, voluntary healthcare providers or patient reporters." (ECF No. 70 at 8.)[4] The Court is not persuaded.

Indeed, other courts also have rejected the interpretation Defendant urges here. Thus, despite Defendant's insistence that 21 U.S.C. § 360i(b)(3) bars the discovery of its complaint files, some courts have concluded that complaint files and related documents are subject to discovery. *See, e.g., Ascenzo v. Medtronic Minimed, Inc.*, No. 05CIV3610SCRMDF, 2007 WL 9817973, at *1 (S.D.N.Y. May 31, 2007) (finding defendant's "complaint files or database" subject to discovery and rejecting defendant's argument that its complaint records were protected by 21 U.S.C.§ 360i(b)(3)); *Contratto v. Ethicon, Inc.,* 225 F.R.D. 593, 598 n.10 (N.D. Cal. 2004) ("Section 360i(b)(3) by its own terms does not apply to a manufacturer's complaint files." Unlike here, the defendant conceded that the statute did not cover its complaint files but similar to here, had contended that because the initial complaint fell within the statute, then all documents generated by the complaint should likewise be protected); *see also Adcox v. Medtronic, Inc.,* 131 F. Supp. 2d 1070, 1074 (E.D. Ark. 1999) (finding complaints made by patients or their legal representatives to be discoverable, but only after redaction of reporter and patient identifying information). The Court finds the reasoning of the above authority persuasive and applies it here. In so doing, the Court notes, as other courts have, that the type of information Plaintiff seeks here routinely would be discoverable in a products liability suit in the absence of § 360i(b)(3). *See Ascenzo,* at *3. Thus, the Court concludes that Defendant's complaint files and product complaints relating to the "Rib Plate" (Model Number 24-015-22-71) ("20 hole, 1.5 mm thick X-shape rib fixation plate") are not protected from discovery under §

[4] Beyond this, Defendant asserts by footnote that *Davol*, "is premised upon an incorrect understanding of the regulatory framework, and inaccurate conclusions regarding relevant case law." (ECF No. 70 at 9 n.13.)

360i(b)(3). To this extent, the motion for a protective order is **DENIED** and the motion to compel is **GRANTED.** Defendant is **DIRECTED** to produce these documents to Plaintiff within **FOURTEEN DAYS OF THE DATE OF THIS OPINION AND ORDER.** As discussed above, Plaintiff has agreed to redactions as appropriate. (ECF No 65 at 5 n.5.)

Because Defendant's overbreadth and undue burden arguments are both undeveloped and likely impacted by the limitations the Court has imposed on discovery herein, the Court will not consider these concerns as any further basis for a protective order. To the extent Defendant cites a discovery period of "nearly two decades" as overbroad and burdensome on its face, this conclusory allegation is not persuasive. Indeed, the Court notes that a discovery period of seventeen years, standing alone, is not necessarily subject to limitation. *See, e.g., Reising,* 2018 WL 5489568, at *5 (allowing Plaintiff to obtain 15 years' worth of information on residential lawn mowers). Further, as to the matter of a privilege log, Defendant has represented that, in the event the Court finds any information to be discoverable, it will provide one that is compliant with the Federal Rules of Civil Procedure. Thus, to the extent that Defendant believes that any information found to be discoverable here is subject to some privilege protection, it shall produce any such privilege log within **FOURTEEN DAYS OF THE DATE OF THIS ORDER.**

This brings the Court to the matter of Defendant's obligation to obtain relevant documents in KLM's possession. Although the specific documents sought are not well-defined in the parties' briefing, consistent with this Opinion and Order and as reflected in the discovery requests at issue, the Court concludes that these documents include the internal complaint files

maintained by KLM for the "Rib Plate" (Model Number 24-015-22-71) (further described as a "20 hole, 1.5 mm thick X-shape rib fixation plate).[5]

As noted above, Defendant argues that it is an entity distinct from KLM and, therefore, it does not possess or control KLM's documents and otherwise has no right to access or obtain them. In support of its position, Defendant has submitted the Affidavit of William Ticoras, its President. (ECF No. 58-12.) According to Mr. Ticoras, Defendant is an operational entity which sells and distributes various craniomaxillofacial and sternal thoracic products and services in the United States, including but not limited to, products manufactured by KLM. (*Id.* at § 4.) Further, Mr. Ticoras attests that KLM has no financial interest in this action; KLM owns no interest directly or indirectly in Defendant and Defendant owns no interest directly in KLM; Defendant has no contractual or other right to compel KLM's documents; Defendant is not typically provided with copies of KLM documents relating to design, manufacturing, or testing; it does not have actual possession of any documents prepared and maintained by KLM other than those provided in the ordinary course of their business relationship; and if Defendant asks KLM for documents, it is strictly up to KLM as to whether to honor the request. (*Id*. at §§ 9-10, 13-16.)

For her part, Plaintiff argues that Defendant may have engaged in "deceptive conduct" in the course of the briefing cycle on these motions by removing language from its website indicating that it was a subsidiary of KLM and including language indicating that it is a U.S. importer and distributor. Plaintiff suggests that this change was undertaken to intentionally deprive her of relevant evidence.

Initially, the Court finds no merit to Plaintiff's argument here. Certainly, a subsidiary may be deemed to have control over a parent corporation's documents under certain circumstances. *See Robert Bosch LLC v. Snap-On Inc.,* No. 12-11503, 2013 WL 823330, at *2 (E.D. Mich. Mar. 6,

[5]There is some indication in the briefing that Plaintiff also seeks information relating to KLM's CAPA-reporting. To the extent this is so, for the same reasons discussed, Defendant has neither a legal right nor the practical ability to obtain them from KLM.

2013). However, Mr, Ticaro's affidavit explaining the relationship between Defendant and KLM does not describe it in terms of a parent/subsidiary relationship. Significantly, it is dated August 10, 2022. This date precedes by more than a month the date highlighted by Plaintiff as the date it cited to Defendant's website representations in its filings in this litigation. So, beyond the dubiousness of Plaintiff's expectation that the Court would find the evidentiary value of website representations to exceed that of a sworn affidavit, the timeline does not comport with Plaintiff's theory.

On a more substantive note, "[t]he Sixth Circuit has held that "documents are deemed to be within the 'possession, custody, or control' for purposes of Rule 34 if the party has *actual* possession, custody or control, or has the legal right to obtain the documents on demand." *St. Clair Cnty. Employees' Ret. Sys. v. Acadia Healthcare Co., Inc.*, No. 3:18-CV-00988, 2022 WL 4095387, at *9 (M.D. Tenn. Sept. 7, 2022) (quoting *In re Bankers Tr. Co.*, 61 F.3d 465, 469 (6th Cir. 1995) (emphasis in original)). Applying this precedent, some courts have construed the "legal right" standard narrowly while other courts have found that control includes the practical ability to produce documents from a third party. *Id*. On the current record, Plaintiff's contention that Defendant has a right to KLM's documents fails under either test.

As for a legal right to the documents, Mr. Ticora's sworn statements confirm that Defendant has no such right to documents in KLM's possession. However, whether a party has a sufficient degree of control over requested documents to constitute a practical ability to obtain the documents is a question of fact. *St. Clair Cnty.,* 2022 WL 4095387, at *10 (citing 8B Charles Alan Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ. § 2210 (3d ed.) ("The concept of 'control' is very important in applying [Rule 34], but the application of this concept is often highly fact-specific."). "'Particular concerns can arise when a corporate party is related to

another corporation, and this nonparty corporation actually possesses the materials in question.'" *Id*. In this circumstance, "[r]ather than adopting an overarching rule . . . courts have tended to focus on the facts shown in a particular case." *Id.* Important factors to be considered include "the existence of cooperative agreements . . . between the responding party and the non-party, the extent to which the non-party has any stake in the outcome of the litigation, and the non-party's history of cooperating with document requests." *Gross v. Lunduski*, 304 F.R.D. 136, 142 (W.D.N.Y. 2014) (quoting *Alexander Interactive, Inc.,* 2014 WL 61472, at *3 (citing cases)).

Mr. Ticora's Affidavit confirms that there are no cooperative agreements between Defendant and KLM; that KLM has no financial stake in this litigation; and that any decision to provide documents to Defendant is completely within KLM's control and discretion. Plaintiff has presented no meaningful evidence to the contrary. Thus, on this record, the Court cannot conclude that Defendant has the practical ability to obtain access to KLM's documents. Accordingly, the motion for a protective order is **GRANTED** as to any relevant documents in KLM' possession and the motion to compel is **DENIED.**

Finally, given the resolution of the cross-motions, the Court cannot conclude, as urged by Plaintiff, that Defendant's discovery conduct warrants an award of sanctions. Similarly, the Court declines to issue a pre-emptive prohibition on any future discovery requests as suggested by Defendant's motion.

IV.

For the foregoing reasons, Defendant's Motion for a Protective Order (ECF No. 58) is **GRANTED, in part** and **DENIED, in part**. Defendant's request for oral argument is **DENIED.** Plaintiff's Motion to Compel (ECF No.65, as amended by ECF No. 71) is **GRANTED, in part** and **DENIED, in part**. Plaintiff's motion for leave (ECF No.71) is **GRANTED** as unopposed.

Plaintiff's request for sanctions is **DENIED.** Defendant is **DIRECTED** to produce a privilege log and appropriately redacted documents as described above to Plaintiff within **FOURTEEN DAYS OF THE DATE OF THIS OPINION AND ORDER.**

IT IS SO ORDERED.

Date: January 27, 2023

/s/ Elizabeth A. Preston Deavers
ELIZABETH A. PRESTON DEAVERS
UNITED STATES MAGISTRATE JUDGE